CLAIMS AMENDMENTS:

Please cancel claims 23, 24, 25 and 26 without prejudice.

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claim 1 (canceled)

Claim 2 (canceled)

Claim 3 (canceled)

Claim 4 (canceled)

Claim 5 (canceled)

Claim 6 (canceled)

Claim 7 (canceled)

Claim 8 (canceled)

Claim 9 (canceled)

Claim 10 (canceled)

Claim 11 (canceled)

Claim 12 (canceled)

Claim 13 (canceled)

Claim 14 (canceled)

Claim 15 (canceled)

Claim 16 (canceled)

Claim 17 (canceled)

Claim 18 (canceled)

Claim 19 (canceled)

Claim 20 (canceled)

21. (Currently amended) A screening method for identifying agent compounds capable of increasing 27-hydroxy-7-dehydrocholesterol (cholesta-5,7-diene-3ß-27 diol) and/or 27-hydroxy-

8-dehydrocholesterol (cholesta-5,8-diene-3ß-27 diol) levels in a cell or an animal, wherein said compound interferes with the expression of 27-hydroxy-7-dehydrocholesterol reductase activity ~~or stimulates expression of 27-hydroxylase activity~~, comprising determining the levels of 27-hydroxy-7-dehydrocholesterol and/or 27-hydroxy-8-dehyrocholesterol in the presence and absence of a compound, and selecting ~~wherein~~ a compound which ~~stimulates 27-hydroxylase or reduces 27-hydroxy-7-dehydrocholesterol reductase relative to a control is identified as a compound capable of increasing~~ increases 27-hydroxy-7-dehydrocholesterol and/or 27-hydroxy-8-dehydrocholesterol relative to the levels in the absence of the compound.

22. (Previously presented) The method of claim 21, wherein a compound is selected ~~that interferes with the expression of 27-hydroxy-7-dehydrocholesterol reductase activity is identified~~ as a compound capable of increasing 27-hydroxy-7-dehydrocholesterol and/or 27-hydroxy-8-dehydrocholesterol levels relative to the levels in the absence of the compound and wherein the expression of 27-hydroxylase, as determined by measuring its encoding mRNA CYP27, is not altered in the presence of the compound.

Claim 23 (Canceled)

Claim 24 (Canceled)

Claim 25 (Canceled)

Claim 26 (Canceled)

REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated September 11, 2007.

Status of the Claims

Claims 21-26, directed to screening methods, were pending. The Examiner has determined that new claim 21 in part, claim 23, and claims 24-26 do not correspond to the elected invention. Accordingly she has deemed claims 23 and 24-26 withdrawn from consideration as being

directed to a non-elected invention. Thus, the Examiner has examined the following: (a) claim 21 to the extent that it reads on methods for identifying a compound that interferes with the expression of 27-hydroxy-7-dehydrocholesterol reductase activity; and (b) claim 22, drawn to a method for identifying agents capable of interfering with the expression of 27-hydroxy-7-dehydrocholesterol reductase activity.

Applicants have canceled claims 23-26, which the Examiner deems withdrawn, without prejudice. Claims 21 and 22 have been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention, including to more particularly direct the claims to the elected invention. Support for the amendments to the claims may be found generally throughout the specification. Allowance of the pending claims is respectfully requested.

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Maintained Rejections

Specification

The Examiner has again objected to the specification disclosure with regard to the Figures. The Examiner remarks that the previously amended brief description of the drawings does not reflect the content of the figures, particularly in as much as replacement drawings were not submitted with Applicants Response on December 14, 2007. Applicants submit concurrently herewith replacement drawings reflecting the corrected Figure numbering and lettering, and now corresponding to Figures 1-3. In addition, Applicants have above amended the specification at page 7 paragraph [0026] in the brief description of Figure 1A, 1B, and 1C to correct a word, specifically revising characteristics to "characteristic". Applicants submit that this does not constitute new matter. Applicants respectfully request the amendment to the drawings

description in the specification and the replacement drawings be accepted and this objection be withdrawn.

The Specification Fully Enables the Claimed Invention

The Examiner has maintained his rejection of claim 17, now canceled, over new claim 22 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most connected, to make and/or use the invention. The Examiner argues that the scope of the invention as embraced by claim 22 is not commensurate with the disclosure. The Examiner asserts that the skilled artisan would be required to first identify, isolate, and reproduce the 27-hydroxy-7-dehydrocholesterol reductase in order to practice the claimed invention.

Applicants respectfully disagree. Applicants have above amended claim 22 to more particularly and clearly claim the elected invention. Applicants assert that the claims, including as amended, relate to screening methods for agents/compounds capable of increasing 27-hydroxy-7-dehydrocholesterol (cholesta-5,7-diene-3ß-27 diol) and/or 27-hydroxy-8-dehydrocholesterol (cholesta-5,8-diene-3ß-27 diol). Applicants submit that this clearly describes and relates to the desired physiological result, an increase in the 27-hydroxy metabolites of 7-dehydrocholesterol or 8-dehydrocholesterol, and that these methods are fully enabled by the specification, including its teachings and examples, particularly in view of the capabilities and knowledge of the skilled artisan. The screening methods of the invention involve identifying agent compounds that increase the 27-hydroxy metabolites of 7-dehydrocholesterol or 8-dehydrocholesterol by determining and assessing the amount of 27-hydroxy-7-dehydrocholesterol and/or of 27-hydroxy-8-dehydrocholesterol. One skilled in the art would know to and be able to determine and assess the amount of 27-hydroxy-7-dehydrocholesterol and/or of 27-hydroxy-8-dehydrocholesterol. Clearly, it is not required to first identify, isolate, and reproduce the 27-hydroxy-7-dehydrocholesterol reductase in order to practice the claimed invention. In claim 22, the additional aspect of determining the mRNA levels of CYP27, which

encodes 27-hydroxylase, and selecting compounds wherein the CYP27 mRNA levels are unaltered in the presence of the compound. One of skill in the art can readily and without undue experimentation determine the levels of CYP27 mRNA. Applicants respectfully submit that claim 22 fully and properly complies with the enablement requirement.

In view of the foregoing remarks and above amendments, Applicants submit that the Examiner's rejection under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

Particularity and Distinctiveness of the Claims

The rejection of claim 17, now canceled under 35 U.S.C. 112, second paragraph, is maintained over new claims 21 and 22, as being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention. New claims 21 and 22, the Examiner states, are directed towards a screening method for identifying agent compounds capable of interfering with the expression of 27-hydroxy-7-dehyrodrocholesterol reductase activity, in part by determining the expression of 27-hydroxylase and its level of non-altered CYP27 mRNA, however the specification is silent about what enzyme is being measured. The Examiner argues that the skilled artisan would be unable to determine the metes and bounds of the claimed invention. Applicants respectfully traverse this rejection. Applicants respectfully submit that claims 21 and 22, including as above amended, are clear and definite and particularly point out and distinctly claim the subject matter. The claims are clearly directed to measurement of the levels of 27-hydroxy-7-dehydrocholesterol and/or 27-hydroxy-8-dehyrocholesterol in the presence and absence of a compound, and selecting a compound which increases 27-hydroxy-7-dehydrocholesterol and/or 27-hydroxy-8-dehydrocholesterol relative to the levels in the absence of the compound. In claim 22, the additional aspect of determining the mRNA levels of CYP27, which encodes 27-hydroxylase, and selecting compounds wherein the CYP27 mRNA levels are unaltered in the presence of the compound. Applicants submit that claims 21 and 22, including as amended, meet the requirements of 35 U.S.C. 112, second paragraph, and are definite.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's rejection is obviated and request that the 35 U.S.C. 112, second paragraph, rejection be withdrawn.

New Grounds of Rejections

Claim Rejections – 35 U.S.C. §112, First Paragraph

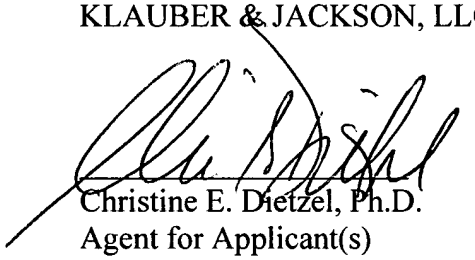
Claims 21 and 22 are rejected under 35 U.S.C. §112, first paragraph, as failing to meet the requirements for written description. The Examiner cites this as a new matter rejection. The Examiner argues that it is not clear that the Applicant was in possession of a genus of undefined compounds "capable of increasing 27-hydroxy-7-dehyrodrocholesterol and/or 27-hydroxy-8-dehyrodrocholesterol levels wherein the expression of 27-hydroxylase, as determined by measuring its encoding mRNA CYP27, is not altered" at the time the Application was filed. Applicants respectfully disagree and assert that claims 21 and 22, including as above amended, meet the written description requirements. Applicants point out that the language of claims 21 and 22 has been amended above in order to more particularly and clearly set out the claimed invention. Further, Applicants point out and underscore that the instant claims are directed to a screening method for identifying agent compounds capable of increasing 27-hydroxy-7-dehydrocholesterol (cholesta-5,7-diene-3ß-27 diol) and/or 27-hydroxy-8-dehydrocholesterol (cholesta-5,8-diene-3ß-27 diol) levels in a cell or an animal, and are not directed to compounds. At issue is whether Applicants have described the method claimed, and not whether a genus of compounds meeting the screening method claim requirements are already in Applicants possession. Applicants submit that the methods of claims 21 and 22 meet the requirements of 35 U.S.C. §112, first paragraph.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's rejection is obviated and request that this 35 U.S.C. 112, first paragraph, rejection be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,
KLAUBER & JACKSON, LLC



Christine E. Dietzel, Ph.D.
Agent for Applicant(s)
Registration No. 37,309

KLAUBER & JACKSON, LLC
411 Hackensack Avenue
Hackensack NJ 07601
Tel: (201) 487-5800

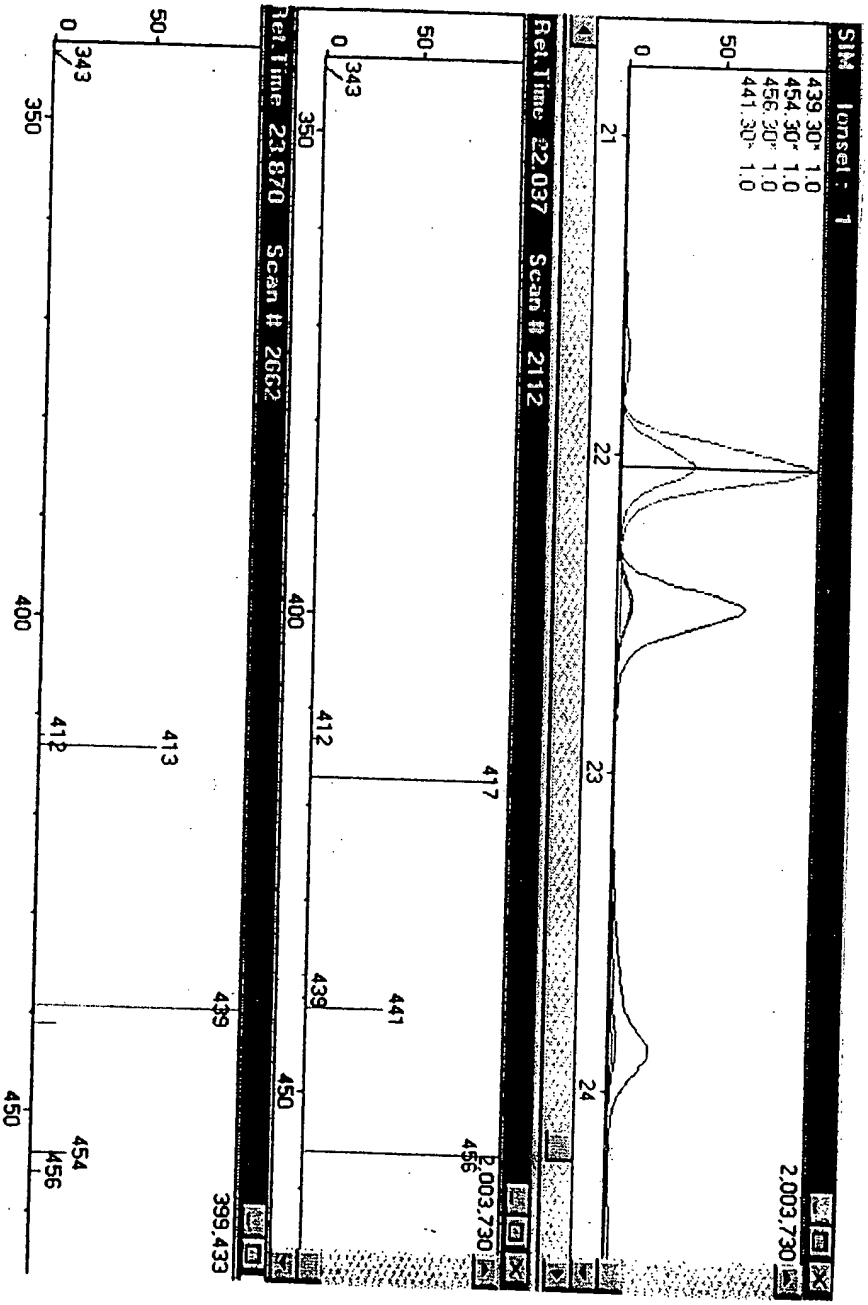

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Figure 1